

REMARKS

Claims 31-47 have been canceled and claims 48-65 have been added. The added claims are supported by now canceled claims 1-47 and Example 10 of the specification.

In the June 13, 2005 Office Action claims 31-47 were rejected under 35 U.S.C. 112, first paragraph, for lack of enablement. The specific grounds for rejection, and applicants' response thereto, are set forth in detail below.

Rejection under 35 USC § 112, first paragraph

Claims 31-47 are rejected for lack of enablement. Specifically, the Examiner admits that the specification is enabling for a method of augmenting vaccination in a fish using TAEK, but asserts that the specification does not enable one skilled in the art to augment vaccination in any host using any 2-9 residue peptide comprising Glx-Lys. The added claims recite methods for vaccinating fish, mooting the first aspect of the rejection with respect to the nature of the host. Applicant respectfully traverses the rejection as directed to the nature of the peptide used in the claimed methods.

A disclosure which contains a teaching of the manner and process of making and using an invention must be taken as in compliance with the enabling requirement of the first paragraph of § 112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support." *In re Marzocchi*, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971). It is the Examiner's burden to establish why one skilled in the art would doubt that other 2-9 residue peptides containing Glx-Lys could be used in the claimed methods.

Here the Examiner seeks to bolster the argument with respect to the nature of the peptide by citing a review that allegedly states that immunostimulating peptides may have widely varying effects. The Examiner also points to how the review contains a single description of how removal of a single arginine amino acid residue from TKPR produces the opposite biological effect. Whether or not this is true, it is not relevant to the peptides recited in the claimed methods. None of the peptides described in the cited review contain the Glx-Lys motif that applicants have shown provides broad immunostimulatory effects and therefore applicant respectfully questions the relevance of the review, which deals with quite different peptides of widely varying structures. Moreover, the lack of scientific context in the results described in the

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review means that no conclusions can be drawn from those results one way or the other. The fact that a single amino acid change from TKPR to TKP produces a change in properties would not be surprising, for example, if the PR motif was responsible for the biological effects of TKPR.

Accordingly, the Examiner has failed to set forth any objective evidence to support the assertion that one skilled in the art would not be able to use 2-9 residue peptides containing a Glx-Lys motif in the claimed methods without undue experimentation. The Examiner has therefore failed to meet the burden required to sustain a rejection for lack of enablement under § 112, first paragraph, and the rejection should be withdrawn.

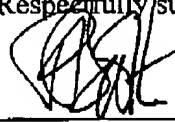
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CONCLUSION

Applicants respectfully submit that the claims are in a condition for allowance. The Examiner is invited to contact the undersigned attorney to resolve any issues, in order to expedite the prosecution of the application.

The Commissioner is hereby authorized by this paper to charge any fees during the entire pendency of this application including fees due under 37 C.F.R. §§ 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 50-3840.

Respectfully submitted,



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